

Decision Memo for Diabetic Peripheral Neuropathy with Loss of Protective Sensation (LOPS) (CAG-00059N)

Decision Summary

This decision memorandum announces the agency's intention to issue a National Coverage Decision covering foot care, that would otherwise be considered routine in the absence of localized illness of the feet, for Medicare beneficiaries with peripheral neuropathy with LOPS as provided or under 42 C.F.R. §411.15 (l)(1)(i).

The diagnosis of peripheral neuropathy with LOPS due to diabetes mellitus should be established and documented prior to coverage of foot care. Other causes of peripheral neuropathy should be considered and investigated by the primary care physician prior to initiating scheduled foot care for persons with LOPS. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament. Five sites should be tested on the plantar surface of each foot, ¹⁸ using the guidelines in the National Institute of Diabetes and Digestive and Kidney Diseases publication "Feet Can Last a Lifetime."¹⁹ The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided.

As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral neuropathy with loss of protective sensation.²⁰

An examination of the feet every six months shall be covered for individuals with diabetic peripheral neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. Although the frequency of foot exams was not specifically addressed in the Litzelman or Patout studies, it appeared that all participants received at least an initial examination and a follow-up visit during the one-year intervention programs. This interval is also suggested for individuals in the moderate-risk category for lower extremity amputations.²¹

[Back to Top](#)

Decision Memo

To: File: CAG-00059
Diabetic Peripheral Neuropathy with Loss of Protective Sensation

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Re: National Coverage Decision

Date: October 17, 2001

This memorandum serves four purposes: (1) outlines the description, detection, prevention, treatment and consequences of peripheral neuropathy in people with diabetes mellitus; (2) analyzes the relevant scientific data related to management of peripheral neuropathy; (3) delineates the reasons why people with diabetes and peripheral neuropathy with loss of protective sensation have localized illness of the feet; and 4) explains why medical care in these instances is reasonable and necessary under § 1862 (a)(1)(A).

The most common diabetic complication leading to hospitalization is foot disease due to ulcerations and other lower extremity complications. Hospital admissions for diabetic foot disorders increased from 25% of diabetic hospital admissions in the late 1960s to over 50% in the 1980s.¹ The amputation risk for people with diabetes is estimated to be 15 to 40 times greater than that of the general population. The health risks associated with diabetic complications is of such great concern that the Surgeon General has expanded the number of diabetes objectives from 5 in Healthy People 2000 to 17 in Healthy People 2010.² Two of those goals are reducing the number of foot ulcers and reducing the rate of lower extremity amputations (LEAs).

People with diabetes comprise approximately 5% of the population, but account for 50% of all non-traumatic LEAs. According to the National Institute of Diabetes and Digestive and Kidney Diseases, between 1993 and 1995 about 67,000 amputations were performed each year among people with diabetes. In 1999, this number increased to 86,000. Amputees with diabetes have a 50% chance of bilateral amputation after 5 years, often as a result of increased wear on the remaining limb.³ Of greater concern, the 3-year survival rate after one major lower extremity amputation is only 50%, and the 5-year survival rate is approximately 40%.⁴

Peripheral neuropathy is the most important factor leading to amputation in people with diabetes. In diabetes, peripheral neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. Approximately 70 percent of diabetics develop neuropathy within 5 years of diagnosis. After 5 years, the incidence increases to almost 100 percent.⁵ Autonomic involvement results in decreased perspiration, dryness, cracking, and fissures of the skin, which become entry points for bacteria. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing. These complications do not occur with other types of peripheral neuropathy.

Currently there is no specific pharmacologic treatment approved in the United States that either prevents or reverses peripheral neuropathy in people with diabetes other than improvements in glucose control. The American Diabetes Association, the American Orthopaedic Foot and Ankle Society, and the American Podiatric Medical Association all agree that foot ulcerations and amputations resulting from foot injuries associated with LOPS are largely preventable. They recommend regular foot examinations to identify high-risk feet consisting of the following:

1. Visual inspection of forefoot and hindfoot (including toe web spaces)
2. History
3. Assessment of
 - protective sensation
 - foot structure and biomechanics
 - vascular status and skin integrity
4. Local care of superficial wounds
5. Assessment for footwear
6. Debridement of corns and calluses
7. Trimming of nails
8. Patient education on prevention and self-care with specific emphasis on early identification of foot complications.

For the reasons noted above, peripheral neuropathy with LOPS is a localized illness of the feet. There are three instances when services that would otherwise be considered routine are considered nonroutine and Medicare covered. These conditions are outlined in the Code of Federal Regulations (C.F.R.)⁶ and described as "localized illness, injury or symptoms involving the feet." Peripheral neuropathy with LOPS as a localized illness falls within the regulation's exception to the general exclusionary rule. Foot exams for people with diabetic peripheral neuropathy with LOPS are reasonable and necessary because of their potential role in early intervention of the serious complications that typically afflict diabetics with the disease.

Benefit Category

Foot care furnished to beneficiaries who have peripheral neuropathy with LOPS, secondary to diabetes, falls under the benefit category of physicians' services as set forth in section 1861(s)(1) of the Social Security Act, and excludes services incident to a physician's services as provided under this section.

Diagnosis of Peripheral Neuropathy

Peripheral neuropathy is a general phrase denoting functional disturbances and/or pathological changes in the peripheral nervous system. It is a manifestation of many conditions including diabetes mellitus, alcoholism, nutritional diseases, connective tissues diseases, nerve entrapment and compressive disorders, infectious diseases, toxin or medication induced conditions, and others. Symptoms may vary depending on whether the neuropathy affects sensory nerves, motor nerves or both.

A number of tests may be used to diagnose peripheral neuropathy with LOPS, including the 5.07 monofilament test, vibration perception threshold (VPT) using a tuning fork, Achilles tendon reflex, and pin prick tests. Of these, the 5.07 monofilament test has emerged as one of the most utilized reference tests. Kumar and colleagues found the 5.07 test to be more sensitive but less specific than the VPT test.⁷ Hau and colleagues found in a prospective study of risk factors that the 5.07 Semmes-Weinstein monofilament test was fairly sensitive (91%) but not very specific (34%).⁸

Recently, Edelman and colleagues have confirmed the reproducibility and accuracy of monofilament test results when performed by a primary care provider.⁹ In this study, the results of a previously validated four-component diabetic foot ulcer risk stratification examination and a vascular disease history and physical examination were compared when performed by a primary care provider and a foot care specialist. The study showed that primary care providers had good sensitivity and specificity for most components of the examination (compared with the foot care specialists examination as the criterion standard), but frequently were unable to identify pedal pulses or foot deformity. McNeely and colleagues stated that "in the clinical setting, sensory examination with a 5.07 monofilament probably remains the single most practical measure of foot ulcer risk assessment."¹⁰

Summary of Evidence to Support Foot Care for Individuals with Diabetic Peripheral Neuropathy with LOPS

Diabetic foot complications are the most common cause of nontraumatic LEA. Individuals with diabetes are at risk for LEA due to a number of factors, including:

- Peripheral neuropathy
- Peripheral vascular disease
- Foot lesions such as ulcers, deformities, infections, nail pathology
- Prior amputation.

In particular, foot ulcers have been targeted for prevention and intervention since foot ulcers precede over 80% of diabetic amputations.¹¹ In the presence of peripheral vascular disease and neuropathy, the development of a foot ulcer may be the start of a chain of events that may lead to amputations. Peripheral neuropathy, secondary to diabetes, may also lead to foot deformities, such as neuroathropathy and Charcot's foot, which may add to the risk of lower extremity events.

The risk of LEA associated with foot ulcers heightens the probable role of proper foot examination and care in detecting disease prior to foot ulcer and reducing subsequent complications. The prevention and early treatment of foot ulcers may contribute to decreasing LEAs in individuals with diabetes.¹² Fundamental to a prevention strategy is risk identification. A few studies have examined the risk factors associated with foot ulcers in the diabetic population (see Table 2).

Table 2. Studies on Risk Factors for Lower Extremity Events

Author, Year	Design, Setting, Characteristics	N	Outcome	Risk Factors (95% CI)	Comments
Boyko 1999	Prospective, VA, Mean age =63.2	577/749 [c/e]*	Diabetic foot ulcer	Foot insensitivity to 5.07 monofilament any location RR=2.2 (1.5-3.1). Past history foot ulcer RR=1.6 (1.6-2.3). Past history amputation RR=2.8 (1.8-4.3).	Ulcer = full thickness skin defect on foot>14 days to heal. Mean follow-up=3.7 years.
Hau 2000	Prospective, Outpatient, Mean age =58+/-12	248 patients with diabetes	Foot ulceration	High NDS OR=3.1 (1.3-7.6). High VPT OR=3.4 (1.7-6.8). High SWF OR=2.4 (1.1-5.3). High foot pressure OR=2.0 (1.2-3.3).	Foot ulcer not defined. NDS=neuropathy disability score (reflexes, sensory). VPT=vibration perception threshold (biothesiometer). SWF=5.07 Semmes-Weinstein monofilament (10g pressure on plantar hallux).
Litzelman 1997	Nested case control, Academic, Mean age =60.4+/-9.6	34 cases 318 controls	Serious foot lesions	Foot insensitivity to 5.07 monofilament OR=2.75 (1.55-4.88). Baseline foot lesion OR=13.41 (3.19-56.26). Low HDL OR=1.63 (1.11-2.39).	Serious foot lesion = at least nonulcerated lesion. Secondary analysis of data from RCT. Multiple statistical analyses
McNeely 1995	Case control, VA, Mean age =60.4+/-10.1	46 cases 322 controls	Foot ulceration	Insensate to 5.07 mono any location OR=18.42 (3.83-88.47). TcPO2<30mm Hg OR=57.87 (5.08-658.96). Absent Achilles tendon reflex OR=6.48 (2.37-18.06).	Nurse practitioner interviewed and collected data. Temporal issues, other methodologic issues

Author, Year	Design, Setting, Characteristics	N	Outcome	Risk Factors (95% CI)	Comments
Pecoraro 1990	Case series, VA, Mean age =63.4+/-11.9	80 cases	Lower extremity amputation	Component causes identified, included ischemia, minor trauma, ulcer, neuropathy, faulty wound healing.	Uncontrolled. Component causes not specifically defined. Issue of reliability.
Reiber 1999	Case series, Academic and VA, Mean age =64.7	148 cases	Lower extremity ulcer	Component causes identified, included neuropathy, minor foot trauma, foot deformity,	Uncontrolled. Neuropathy based on vibratory perception

*sample size completed/enrolled

Overall, peripheral neuropathy with LOPS, as determined usually by insensitivity to the 5.07 monofilament test, was most consistently noted as a significant risk factor for lower extremity events including amputations, ulcers and other lesions. The past history of foot lesions including ulcers and infections was also frequently found to be a significant risk factor.

Comprehensive, multifaceted approaches incorporating multiple interventions that promote greater attention to foot care have been shown to be effectively reduce foot ulcers and other serious foot lesions. Specifically, Litzelman and colleagues were able to reduce serious foot lesions in a randomized controlled trial by utilizing multiple interventions (see Table 3). The intervention was based on two observations (1) basic efforts on the part of the health care provider or patient can reduce the likelihood of subsequent amputation due to diabetes-associated foot disease; and (2) many of these basic procedures are not being systematically applied by health care providers or patients. Over the course of the 12-month study, patients received foot care education and entered into behavioral contracts for desired self-care, which was reinforced with telephone calls and post card reminders. Practice guidelines and informational flow sheets on amputation risk factors were provided to health care providers. Also, patients who received the intervention had special identifiers on their charts to prompt foot examinations and to provide foot care education.

The intervention group (patients in the group that received education on appropriate foot care and whose providers had chart reminders to prompt foot examinations and referral recommendations) was less likely than the control group to have serious foot lesions [baseline prevalence, 2.9%, OR 0.41 (95% CI=0.16-1.00), P = 0.05]. Intervention patients were also more likely to report appropriate self-foot-care behavior, to have foot examinations during office visits (68% compared with 28%; P < 0.001), and to receive foot care education from health care providers (42% compared with 18%; P < 0.001). Finally, physicians in the intervention group were more likely than their control counterparts to examine patients' feet for ulcers, pulses, and abnormal dermatologic conditions and to refer patients to podiatry clinic (10.6% compared with 5.0%; P = 0.04).¹³

Patout and colleagues found similar results when they compared patient outcomes 1 year before and 1 year after enrollment in a comprehensive diabetes lower-extremity amputation prevention program. This study (n=197) was comprised of low income African-Americans referred to the Louisiana State University Health Sciences Center's Comprehensive Diabetes Lower Extremity Amputation Prevention Program (LSUHSC CD_LEAP Program), which is part of the center's Diabetes Foot Program. The program provided case management and care for individuals with at risk feet. Services included education, management of complex nail and callus problems, wound care, and orthotics or specially prescribed footwear, casts, and other devices designed to off-load pressure depending on their risk category. The results of this care were compared to the standard care outcomes 1-year prior to enrollment. Standard care in the community consisted of noncoordinated treatment of foot problems provided in primary care clinics, emergency rooms, and in wound care, surgical, and podiatry clinics.¹⁴ As shown in the table below, the program resulted in substantially reduced ulcer days and hospitalizations. Because of the pre/post design, these results may significantly overestimate the true program benefits.

Table 3. Studies of Comprehensive Foot Care Programs

Author, Year	Design, Setting, Characteristics	N c/e*	Interventions	Outcomes (95% CI)	Comments
Litzelman, 1993	Randomized control trial, Academic, Mean age =60.9+/-9.8	352/395	Patient education, reminders. System reminders. Provider reminders, practice guidelines.	Reduced serious foot lesions OR=0.41(0.16-1.00)	Foot lesion=grade of at least 1.3 (minor nonulcerated lesion...). Multifaceted interventions. 12 month intervention period. Nurse clinicians conducted patient education.
Patout, 2000	Pre-post comparison, Academic, Mean age =55.7+/-10.4 predom. AA	197/300	Foot care education, Foot exams, Footwear, Wound care	Reduced ulcer days by 49%. Reduced hospitalization by 89%.	12 month intervention period. All patients had existing foot conditions. Univariate analysis only.

*sample size completed/enrolled

In addition, Bild and colleagues noted three studies in which multidisciplinary interventions reduced the frequency of LEAs. In Atlanta, Grady Memorial Hospital instituted an integrated inpatient/outpatient diabetes unit, which included comprehensive podiatry services, nurse clinicians and an extensive education program. The annual number of LEAs in this largely African American and indigent cohort decreased by almost 50%, from 172 in 1973 to an average of 92 per year from 1973 to 1982 among 8000 clinic patients.

In London, England a diabetes foot clinic at Kings College Hospital added podiatrists and shoe fitters to the diabetes foot clinic. Over a two-year period emphasizing podiatric care, antibiotic therapy, and specially constructed shoes, the amputation rate declined 44%. The effect of specially fitted footwear on recurrent ulcers was particularly dramatic. Patients receiving specially fitted footwear had an ulcer recurrence rate of 26%, compared to 83% among those with regular shoes.

Similarly, at the University Hospital of Geneva an 85% reduction in below knee amputations was observed over a 4-year period after the initiation of patient education and training in foot care for people with diabetes. He concluded that the results support the notion that comprehensive foot care, including podiatric care, education and specially fitted shoes¹⁵, can reduce LEAs in individuals with diabetes.¹⁶

As with the Patout study, the observational nature of each of these studies raises doubts about the true magnitude of any beneficial effect. In addition, it is noteworthy that all of these studies addressed multidisciplinary or multifactorial interventions for diabetic feet. Patient education, for example may be a critical component, and was included in most of these programs.

CMS Analysis

Overall, several studies on patients with diabetes have evaluated risk factors for lower extremity events such as foot ulceration and amputation. Peripheral neuropathy with LOPS, as determined usually by insensitivity to the 5.07 monofilament test, was most consistently noted as a significant risk factor. The past history of foot lesions including ulcers and infections was also frequently found to be a significant risk factor. In particular, Litzelman and colleagues noted that "patients with baseline foot lesions were about 13 times more likely to have a foot lesion at the 1-year follow-up, compared with patient without lesions at baseline."¹⁷ Although the risk is greater for the diabetic patients with a past history of some foot lesion or infection, the potential impact and benefit from a coverage policy would be substantially greater if applied to the more general population of diabetic patients with peripheral neuropathy and LOPS.

In addition, two specific studies including one randomized controlled trial and one general review article were reviewed to assess the strength of the evidence supporting foot care. In general, the studies showed that foot care provided in multifaceted programs was effective in reducing the number of foot ulcers. Since much of the evidence was observational and indirect, the true magnitude of the effect may be difficult to estimate. However, considered together with the evidence of increased risk for lower extremity events, scheduled foot care for diabetic patients with peripheral neuropathy and LOPS will likely improve outcomes and provide an important benefit for the Medicare population.

Despite limitations in empirical evidence, it is clear that patients with peripheral neuropathy with LOPS are at risk for serious complications that may be preventable to some degree. We therefore conclude that foot care services in this population are not routine, but are reasonable and necessary services. Providing greater access to foot care for patients with diabetic peripheral neuropathy with LOPS will have an important medical benefit.

Due to the indirect nature of the evidence and modest quality of studies, CMS will be analyzing the impact of this newly covered service on outcomes of patients with diabetic peripheral neuropathy and LOPS. Also, we plan to repeat a review of the literature within two years and encourage the professional community to conduct high quality studies to evaluate the effectiveness of scheduled foot care for patients with this disorder. A clear demonstration of benefit from foot care may allow CMS to consider extending this coverage to a broader subpopulation of patients with diabetes and earlier signs of sensory neuropathy.

Since diabetes mellitus is only one of many conditions that may lead to peripheral neuropathy, other causes of peripheral neuropathy should be investigated, mainly by history and basic physical examination and laboratory studies.

Decision

This decision memorandum announces the agency's intention to issue a National Coverage Decision covering foot care, that would otherwise be considered routine in the absence of localized illness of the feet, for Medicare beneficiaries with peripheral neuropathy with LOPS as provided or under 42 C.F.R. §411.15 (l)(1)(i).

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An examination of the feet every six months shall be covered for individuals with diabetic peripheral neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. Although the frequency of foot exams was not specifically addressed in the Litzelman or Patout studies, it appeared that all participants received at least an initial examination and a follow-up visit during the one-year intervention programs. This interval is also suggested for individuals in the moderate-risk category for lower extremity amputations.²¹

Attachment A

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1 Nowak et al. (2000).

2 Healthy People 2010 (2000)

3 Stone and Cianci (1997)

4 Frykberg (1997)

5 Nowak et al. (2000)

6 42 C.F.R. § 411.15 (l)(1)(i)

7 Kumar et al. (1991)

8 Hau et al. (2000)

9 Edelman et al. (1998)

10 McNeely et al. (1995)

11 Pecoraro et al. (1990)

12 Boyko et al. (1999)

13 Litzelman et al. (1993)

14 Patout et al. (2000)

15 Special shoes for people with diabetes are Medicare benefit under the Part B program. See §1861(s)(R)(c)

16 Bild et al (1989) review article

17 Litzelman et al. (1997)

18 Specificity of the 5.07 monofilament to detect an insensate foot at each of the five sites is at 90%. See McGill et al. (1999)

19 <http://www.niddk.nih.gov/health/diabetes/feet/feet2/>

20 See also Perkins et al. (2001)

21 Plummer and Albert (1995)

[Back to Top](#)